IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of:	)	
	)	
Inventor: William P. Van Antwerp	)	Examiner: Bradley James Osinski
	)	
Serial No.: 10/616,784	)	Group Art Unit: 3767
	)	
Filed: July 10, 2003	)	Appeal No.: _____
	)	

Title: METHODS AND COMPOSITIONS FOR THE INHIBITION OF BIOFILMS ON MEDICAL DEVICES

BRIEF OF APPELLANTS

MAIL STOP APPEAL BRIEF - PATENTS
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

In accordance with 37 CFR §41.37, Appellants hereby submit the Appellants' Brief on Appeal from the final rejection in the above-identified application, as set forth in the Office Action dated September 19, 2010.

Please charge the amount of $540.00 to cover the required fee for filing this Appeal Brief as set forth under 37 CFR §41.37(a)(2) and 37 CFR §41.20(b)(2) to Deposit Account No. 50-0494 of Gates & Cooper, LLP. Also, please charge any additional fees or credit any overpayments to Deposit Account No. 50-0494.

I. REAL PARTY IN INTEREST

The real party in interest is Medtronic MiniMed, Inc., the assignee of the present application.

II. RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences for the above-referenced patent application.

III. STATUS OF CLAIMS

The Application as filed included claims 1-35. During prosecution of the instant Application, claim 1 was amended, claims 2 and 10-35 were cancelled and claims 36-41 were added. Claims 1, 3-9 and 36-41 are pending in the application.

Claims 1, 3-6, 8, 9 and 37-41 were rejected under 35 U.S.C. §103(a) as being obvious in view of Gu et al., World Journal of Microbiology and Biotechnology (Gu) and Steinberg et al., Biodegradation (Steinberg), and these rejections are being appealed.

Claim 7 was rejected under 35 U.S.C. §103(a) as being obvious in view of Gu, Steinberg and Schrier et al., U.S. Patent 6,197,598 (Schrier), and this rejection is being appealed.

Claim 36 was rejected under 35 U.S.C. §103(a) as being obvious in view of Gu, Steinberg and Cioanta et al., U.S. Publication 2002/0082556 (Cioanta).

IV. STATUS OF AMENDMENTS

No amendments to the claims have been made subsequent to the final Office Action.

V. SUMMARY OF CLAIMED SUBJECT MATTER

Briefly, Appellants' invention, as recited in independent claims 1 and 38, is generally directed to a medical device having a surface coated with a composition comprising a lectin. In this invention, the lectin is selected for its ability to bind to a compound produced by a microorganism capable of forming a biofilm on the surface of the medical device in order to enhance attachment of the microorganism to the composition comprising the lectin. The lectin is disposed within a biodegradable polymer composition that can slough away from the surface of the medical device when the lectin is bound to the compound produced by a microorganism. The material properties of the lectin (i.e. the ability to promote microbial adhesion) in combination with the material

properties of the polymer composition (i.e. the ability to slough away from the medical device) function to inhibit formation of a biofilm on the surface of the medical device.

Referring to the specification by page and line number for the disclosure of the subject matter recited in independent claims 1 and 38, see original claims 1, 3 and 20 at page 39-40, and paragraph [0103]. Referring to the specification by page and line number for the disclosure of the subject matter recited in dependent claims 3-9, 36, 37, and 39-41, see original claims 3-9 at pages 39-40, and paragraph [0103]-[0104].

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Whether claims 1, 3-6, 8, 9 and 37-41 are unpatentable under 35 U.S.C. §103(a) as being rendered obvious by Gu and Steinberg.

Whether claim 7 is unpatentable under 35 U.S.C. §103(a) as being rendered obvious by Gu, Steinberg and Schrier.

Whether claim 36 is unpatentable under 35 U.S.C. §103(a) as being rendered obvious by Gu, Steinberg and Cioanta.

VII. ARGUMENT

A. Independent Claims 1 and 38 Are Patentable Over The Prior Art

As noted above, Appellants' invention as recited in claims 1 and 38 comprises a medical device coated with lectins capable of binding microorganisms. The material properties of the lectins recited in Appellants' claims (i.e. the ability to bind microorganisms) operate in combination with the material properties of the claimed polymer compositions (i.e. the ability to slough away from the medical device) so as to inhibit formation of a biofilm on the surface of the medical device.

Appellants respectfully traverse the outstanding obviousness rejections to claims 1 and 38 over combinations of Gu and Steinberg because those of skill in this art would not agree with the Patent Office's characterization of the teachings in Gu, for example the assertion that:

> "Gu discloses **a catheter coated with a heavy metal (page 177) that is coated with lectins capable of binding microorganisms** that form a biofilm on the surface of a medical device" (page 2 of the Final Office Action dated September 19, 2009, emphasis added)

Contrary to this assertion, Gu does not disclose a catheter coated with lectins capable of binding microorganisms. Instead, Gu explicitly teaches that their lectins block microbial binding to the catheter by a completely different mechanism, one that involves "**blockage of binding sites by lectins that are otherwise available for bacterial exopolysaccharides**" (see, e.g., the first sentence in column 2 on page 177 of Gu). Because Gu directs artisans to use lectins that operate by binding to, and competitively blocking sites on the surface of the catheter that are bound by microbial factors such as exopolysaccharides (so as to make them inaccessible to exopolysaccharides), the skilled artisan would not agree with the Patent Office's assertion that Gu's invention comprises lectins capable of binding microorganisms that form a biofilm on the surface of a medical device (i.e. as argued by Office Action to make the instant rejection under 35 U.S.C. §103(a)).

One of skill in the art would further disagree with the Patent Office's assertion that the deficiencies in the Gu disclosure are remedied by combining it with the disclosure in Steinberg because:

> "Steinberg presents evidence that increasing the absorption of bacteria on a surface that is degradable/sloughing away (as Gu gives examples of) is a way of inhibiting biofilm growth on the surface of a device/organism" (page 2 of the Final Office Action dated September 19, 2009)

In disagreeing with this assertion, the skilled artisan would note that while Gu mentions chemical compounds that can be included in compositions that can be formulated to be biodegradable (e.g. cellulose acetate), Gu does not teach or suggest the use of biodegradable polymers with their invention because the use of such polymers would compromise the operability of lectins used in their coated catheters (thereby rendering them unsatisfactory for their intended purpose). Specifically, as noted in the first sentence in column 2 on page 177 of Gu, the lectins used to coat their catheters BLOCK microbial adhesion by binding to and blocking sites on the catheter that are otherwise bound by bacterial exopolysaccharides. Consequently, if such lectins were disposed in a coating designed to slough away from the surface of a device, their resultant removal from the surface of the device would prevent them from blocking the binding sites that are otherwise

available for binding by bacterial exopolysaccharides, thereby compromising the operability of the Gu invention. For this reason, one of skill in the art could not have combined the disclosure in Gu with the disclosure in Steinberg in a manner that results in the claimed invention.

As noted above, if the bacterial adhesion blocking lectins that Gu teaches are useful as catheter coatings were disposed in a coating composition modified so as to allow it to slough away from the surface of this device (i.e. in a manner akin to the shedding disclosed in Steinberg), this modification to the Gu invention would compromise its operability by preventing Gu's lectins from blocking bacterial exopolysaccharide binding sites (i.e. because they will have sloughed away). For this reason, any modification to invention disclosed in Gu that results in the lectins sloughing away from the catheter surface would make such coatings unsatisfactory for their intended purpose. As noted for example in M.P.E.P. 2143.01(V), if a proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. See, e.g. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984). Because this occurs in the instant situation, Appellants respectfully request a withdrawal of the rejections to claims 1 and 38 that are predicated on combinations of Gu and Steinberg.

In addition, Appellants once again emphasize the fact that Gu teaches lectins that operate by competitively blocking binding sites on the surface of a medical device that are otherwise available for binding by bacterial exopolysaccharides. In contrast, the lectins recited in claims 1 and 38 function via a completely different principle of operation, that is by binding "a compound produced by a microorganism capable of forming a biofilm on the surface of the medical device". As noted for example in M.P.E.P. 2143.01(VI), if a proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims prima facie obvious. See, e.g. *In re Ratti,* 270 F.2d 810, 123 USPQ 349 (CCPA 1959). Because this occurs in the instant situation, Appellants respectfully request a withdrawal of the rejections to claims 1 and 38 that are predicated on combinations of Gu and Steinberg.

In summary, because those of skill in this technology would not agree with the Patent Office's assertion that Gu discloses a catheter coated with lectins capable of binding microorganisms

and further because the combinations/modifications of Gu and Steinberg that are argued by the Patent Office would in fact render the Gu invention unsatisfactory for its intended purpose (as well as change the principle of operation of the lectins of the Gu invention), the Patent Office has failed to meet the threshold for a finding of obviousness under 35 U.S.C. §103(a). For these reasons, a withdrawal of all rejections under 35 U.S.C. §103(a) that are predicated on combinations of Gu and Steinberg is respectfully requested.

B. The Dependent Claims Are Patentable Over The Prior Art

An analysis of the Schrier and Cionata disclosures shows that they fail to remedy the above-noted deficiencies of the Gu and Steinberg disclosures. The Schrier disclosure merely teaches a specific lectin recited in dependent claim 7 (i.e. concanavalin A, a binder lectin for *Pseudomonas aeruginosa).* The Cioanta disclosure merely teaches a specific device material recited in dependent claim 36 (i.e. catheters composed partially of titanium or stainless steel). Consequently, dependent claims 3-9, 36, 37, and 39-41 are also submitted to be allowable over Gu, Steinberg, Schrier and Cionata in the same manner as independent claims 1 and 38, because they are dependent on independent claims 1 and 38, respectively, and thus contain all the limitations of the independent claims. In addition, dependent claims 3-9, 36, 37, and 39-41 recite a number of additional novel elements not shown by Gu, Steinberg, Schrier and Cionata. Thus, the Appellants submit that dependent claims 3-9, 36, 37 and 39-41 are also allowable over Gu, Steinberg, Schrier and Cionata.

C. Conclusion

In light of the above arguments, Appellants respectfully submit that the cited references do not anticipate nor render obvious the claimed invention. More specifically, Appellants' claims recite novel physical features which patentably distinguish over any and all references under 35 U.S.C. §§ 102 and 103. As a result, a decision by the Board of Patent Appeals and Interferences reversing the Examiner and directing allowance of the pending claims in the subject application is respectfully solicited.

Respectfully submitted,

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G&C 130.62-US-01

APPENDIX

1. (PREVIOUSLY PRESENTED) A medical device having a surface coated with a composition comprising a lectin, wherein:

(a) the medical device includes a metallic material:

(b) the lectin binds a compound produced by a microorganism capable of forming a biofilm on the surface of the medical device so as to enhance attachment of the microorganism to the composition comprising the lectin; and

(c) the lectin is disposed within a biodegradable polymer composition that can slough away from the surface of the medical device when the lectin is bound to the compound produced by a microorganism,

so as to inhibit formation of a biofilm on the surface of the medical device.

2. (CANCELLED)

3. (ORIGINAL) The medical device of claim 2, wherein the biodegradable polymer is a biocompatible polymer that degrades at a controllable rate within an in vivo environment.

4. (ORIGINAL) The medical device of claim 1, wherein the composition further comprises at least one agent that inhibits the growth of the microorganism.

5. (ORIGINAL) The medical device of claim 4, wherein the agent is an antibiotic or an antifungal agent.

6. (ORIGINAL) The medical device of claim 1, wherein the lectin binds to a compound produced by a microorganism selected from the group consisting of Pseudomonas aeruginosa, Streptococcus pneumoniae, Streptococcus viridans, Haemophilus influenzae, Escherichia coli, Staphylococcus aureus, Staphylococcus epidermidis and Candida albicans.

7. (ORIGINAL) The medical device of claim 1, wherein the lectin is wheat germ agglutinin or concanavalin A.

8. (ORIGINAL) The medical device of claim 1, wherein the device is implantable.

9. (ORIGINAL) The medical device of claim 8, wherein the device comprises a drug delivery pump, a pacemaker, a cochlear implant, a shunt, a catheter or a cannula.

10-35. (CANCELLED)

36. (PREVIOUSLY PRESENTED) The medical device of claim 1, wherein the metallic material is titanium or stainless steel.

37. (PREVIOUSLY PRESENTED) The medical device of claim 1, wherein the medical device further includes a biostable polymeric material.

38. (PREVIOUSLY PRESENTED) A medical device having a surface coated with a composition comprising a lectin, wherein:

(a) the surface of the medical device includes a biostable polymeric material;

(b) the lectin binds a compound produced by a microorganism capable of forming a biofilm on the surface of the medical device so as to enhance attachment of the microorganism to the composition comprising the lectin; and

(c) the lectin is disposed within a biodegradable polymer composition that can slough away from the biostable polymeric material when the lectin is bound to the compound produced by a microorganism,

so as to inhibit formation of a biofilm on the surface of the medical device.

39. (PREVIOUSLY PRESENTED) The medical device of claim 38, wherein the biostable polymeric material comprises polytetrafluoroethylene.

40. (PREVIOUSLY PRESENTED) The medical device of claim 38, wherein the medical device further includes a metallic material.

41. (PREVIOUSLY PRESENTED) The medical device of claim 1 or claim 38, wherein the composition comprising the lectin is disposed on a region of the device having a mechanical structure that is compatible with the adherence of microorganisms.

EVIDENCE APPENDIX

None.

RELATED PROCEEDINGS APPENDIX

None.